IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

DALE BURNINGHAM and LANA BURNINGHAM, Plaintiffs, v. WRIGHT MEDICAL GROUP, INC., WRIGHT MEDICAL TECHNOLOGY, INC., Defendants.	**MEMORANDUM DECISION AND ORDER** Case No. 2:17-CV-92 District Judge Jill N. Parrish

Before the Court are Defendants' Motion to Dismiss and Motion to Strike (ECF No. 39). For the reasons below, the Court grants the Motion to Dismiss in part and grants the Motion to Strike in its entirety. Additionally, the Court will certify to the Utah Supreme Court questions regarding the proper application of the unavoidably unsafe exception in strict products liability actions involving implanted medical devices.

I. BACKGROUND

Plaintiffs Dale and Lana Burningham originally filed a complaint in the Superior Court of the State of California for the County of Los Angeles on December 10, 2013. Plaintiffs' complaint alleged that Mr. Burningham sustained injuries from implanted hip devices designed, manufactured, marketed, and sold by Wright Medical Technology.

The Burninghams' case was originally one of hundreds brought against the Wright Defendants in Judicial Council Coordinated Proceeding No. 4710 (the "JCCP"). However, in April 2016, Plaintiffs moved to release their case from the JCCP, remand it to the regular docket of the court to complete discovery, and set it for trial. Defendants did not oppose that motion, but

they did move to dismiss pursuant to the doctrine of *forum non conveniens*. In support of their motion to dismiss, Defendants represented to the California court that, if the action were dismissed, they would consent to the jurisdiction of this Court for purposes of this matter. They also agreed to treat the re-filed action in this Court as if filed on the date it was originally filed in California for statute of limitations purposes.

On November 15, 2016, the California court granted the motion to dismiss, and Plaintiffs filed a complaint in this Court on Febuary 8, 2017. Their complaint alleges three Causes of Action involving the failure of three implanted medical devices: (1) a Profemur Modular Neck implanted in Mr. Burningham's left hip, fractured on February 3, 2012 and revised on February 6, 2012; (2) a metal-on-metal failure of Conserve Components implanted in Mr. Burningham's right hip, revised on February 6, 2012; and (3) a metal-on-metal failure of Conserve Components implanted in Mr. Burningham's left hip, revised on March 27, 2013.

II. MOTION TO DISMISS

Defendants do not move the Court to dismiss the complaint in its entirety. Rather, they argue that a majority of Plaintiffs' claims should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. The Court will briefly review the legal standard and evaluate the relevant claims in turn.

A. LEGAL STANDARD

Rule 8(a)(2) requires that pleadings contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Rule 12(b)(6) permits defendants to challenge the sufficiency of such pleadings on the grounds that they do not state a claim upon which relief can be granted. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Burnett v. Mortg. Elec.*

Registration Sys., 706 F.3d 1231, 1235 (10th Cir. 2013) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

In evaluating the sufficiency of the pleadings, the Court accepts as true all well-pleaded factual allegations and views them in the light most favorable to the plaintiff. *Id.* at 1235. However, "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice to state a claim that can survive a motion to dismiss." *Iqbal*, 556 U.S. at 678. Therefore, "[d]etermining whether a complaint states a plausible claim for relief is a 'context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Burnett*, 706 F.3d at 1236, quoting *Iqbal*, 556 U.S. at 679. "Pleadings that do not allow for at least a 'reasonable inference' of the legally relevant facts are insufficient." *Id.* (quoting *Iqbal*, 556 U.S. at 678). This standard does not, however, require plaintiffs to plead specific facts. The Tenth Circuit has explained:

> The *Twombly/Iqbal* standard is a middle ground between heightened fact pleading, which is expressly rejected, and allowing complaints that are no more than labels and conclusions or a formulaic recitation of the elements of a cause of action, which the Court stated will not do. In other words, Rule 8(a)(2) still lives. Under Rule 8, specific facts are not necessary; the statement need only give the defendant fair notice of what the claim is and the grounds upon which it rests.

Khalik v. United Air Lines, 671 F.3d 1188, 1191 (10th Cir. 2012) (internal quotations, citations, and alterations omitted).

B. CONTESTED CLAIMS

Plaintiffs allege twelve counts divided among three causes of action. For the first cause of action pertaining to the Profemur Modular Neck, Plaintiffs assert claims for "Strict Liability of Wright Medical" (Count I); "Negligent Misrepresentation" (Count II); "Negligent Failure to Warn" (Count III); "General Negligence of Wright Medical" (Count IV); "Negligence Per Se" (Count V); and "Breach of Express Warranty by Wright Medical" (Count VI). The counts

contained in Plaintiffs' second and third causes of action are identical and arise from the metal-on-metal failure of the Conserve Components in Mr. Burningham's right and left hips, respectively. Those counts are "Strict Product Liability" (Count I); "Negligence" (Count II); and "Negligent Misrepresentation" (Count III). The Wright Defendants move the Court to dismiss Plaintiffs' claims for strict liability design defect, breach of warranty, and negligent misrepresentation.

1. Strict Liability Design Defect

Each of Plaintiffs' three causes of action alleges design defect claims arising under a theory of strict liability. Defendants argue that the Profemur Modular Neck and the Conserve Components implanted in Mr. Burningham's hips are "unavoidably unsafe" products and are therefore categorically barred from design defect claims premised on the doctrine of strict liability.

Defendants' argument is based on the Utah Supreme Court's determination in *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991), to adopt the "unavoidably unsafe products" exception to strict products liability as set forth in comment k to section 402A of the Restatement (Second) of Torts (1965) ("comment k"). Comment k suggests that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." However, despite their dangerous nature, they are tremendously beneficial and should not be held to a strict liability standard. Comment k gives the example of the rabies vaccine, which can lead to "very serious and damaging consequences when it is injected." *Id.* But untreated rabies "invariably leads to a dreadful death," so "the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve." *Id.* In *Grundberg*, the court held that "a drug approved by the United States Food and Drug Administration . . . properly prepared, compounded, packaged, and distributed, cannot as a

matter of law be 'defective' in the absence of proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with FDA approval."

Defendants argue that the doctrine regarding unreasonably unsafe products "applies equally to medical devices like the Profemur Modular Neck and Conserve Components at issue." ECF No. 39 at 6. They correctly note that Utah recognizes the doctrine as applied to FDA-approved drugs and that Utah applies the doctrine categorically, rather than on a case-by-case basis. But they cite no authority suggesting that Utah applies the doctrine to implanted medical devices in addition to FDA-approved drugs. Defendants point to decisions from courts in Oklahoma, Washington, California, and Pennsylvania, which do apply the doctrine to implanted medical devices. But in this case, the Court must apply the law of Utah—not the law of these other states.

In essence, Plaintiffs ask this Court to hold that Utah's categorical exception from strict liability for FDA-approved drugs extends to implanted medical devices. But the question of whether the categorical exception applies to implanted medical devices is a question of first impression for Utah courts. Because there is no controlling Utah law on this issue, which will likely recur in future cases, and because its resolution will materially affect the validity of Plaintiffs' claims, the Court *sua sponte* will issue an order certifying the issue to the Utah Supreme Court.[1] For now, the Court will defer ruling on Plaintiffs' design defect claims arising in strict liability.

[1] Rule 41(a) of the Utah Rules of Appellate Procedure provides that "the Utah Supreme Court may answer a question of Utah law certified to it by a court of the United States when requested to do so by such certifying court . . . if the state of the law of Utah applicable to a proceeding before the certifying court is uncertain." The certification order must state the "question of law to be answered," "that the question certified is a controlling issue of law in a proceeding pending before the certifying court," and "that there appears to be no controlling Utah law." Utah R. App. P. 41(c). Certification is appropriate "when the case concerns a matter of vital public concern, where the issue will likely recur in other cases, where resolution of the question to be certified is outcome determinative of the case, and where the state supreme court has yet to have an opportunity to illuminate a clear path on the issue." *Carranza v. United States*, 2009 WL 1392839, at *4 (D. Utah May 14, 2009) (quoting *State Farm Mut. Auto. Ins.*

2. Breach of Express Warranty

Count VI of Plaintiffs' first cause of action alleges a breach of express warranty. Defendants argue that this claim must be dismissed because Plaintiffs have not adequately pled reliance. The Court agrees.

In Utah, "[i]t is generally true that reliance is necessary to establish a cause of action for express warranty." *Mgmt. Comm. Of Graystone Pines Homeowners Ass'n on Behalf of Owners of Condominiums v. Graystone Pines, Inc.*, 652 P.2d 896, 900 (Utah 1982). Plaintiffs' complaint alleges that "Wright Medical expressly warranted that the Profemur Total Hip System in general, and the titanium Profemur modular neck in particular, were safe and effective orthopedic devices for patients requiring a total hip arthroplasty." ECF No. 34 at ¶¶ 336. And the complaint lists those particular warranties. However, Plaintiffs fail to allege how those warranties became a basis of the bargain. The complaint contains no allegation that the Defendants' express warranties were ever communicated to Plaintiffs or Mr. Burningham's physicians. The complaint makes the conclusory allegation that "[t]he express warranties, guarantees, representations, statements, and claims made by Defendants Wright Medical was [sic] part of the basis for Plaintiff Dale Burningham's decision to use of [sic] the product[,] and he relied on these express warranties and guarantees in deciding to use the product." *Id.* at ¶ 344; *see also id.* at ¶ 345 (reciting the same as to Mr. Burningham's surgeon). But under *Twombly* and *Iqbal*, the Court accepts well-pleaded factual allegations but disregards conclusory allegations that recite elements of causes of action. Consequently, Plaintiffs' breach of express warranty claim must be dismissed because Plaintiffs have failed to plead facts that could establish reliance.

Co. v. Pate, 275 F.3d 666, 672 (7th Cir. 2001). And the United States Supreme Court has instructed that federal district courts may avail themselves of state certification procedures when facing "[n]ovel, unsettled questions of state law." *Arizonans for Official English v. Arizona*, 520 U.S. 43, 77 (1997).

3. Negligent Misrepresentation

Each of Plaintiffs' three causes of action alleges negligent misrepresentation claims. Again, Defendants argue that these claims must be dismissed because Plaintiffs have not adequately pled reliance. And again, the Court agrees.

To establish liability for negligent misrepresentation in Utah, Plaintiffs must prove injury "by reasonable reliance upon a second party's careless or negligent misrepresentation of a material fact." *Price-Orem Inv. Co. v. Rollins, Brown & Gunnell, Inc.*, 713 P.2d 55, 59 (Utah 1986). With regard to the Profemur Modular Neck, Plaintiffs allege that

> Plaintiff Dale Burningham and/or his surgeon justifiably relied upon Defendants' misrepresentation and omissions in their marketing, advertisements, promotions and labeling concerning these products, including Defendants' representations that the Profemur Hip System devices in general, and the titanium Profemur modular neck specifically, were safe for use in persons such as Plaintiff Dale Burningham.

ECF No. 34 at ¶ 276. But this conclusory allegation, absent well-pled factual allegations to the effect that Mr. Burningham or his surgeon actually read or saw Defendants' misrepresentations, does not withstand the *Twombly/Iqbal* analysis. And with regard to the Conserve Components in both of Mr. Burningham's hips, Plaintiffs do not make even the conclusory allegation that Mr. Burningham or his surgeon relied on Defendants' representations. *See id.* at ¶ 375. Consequently, Plaintiffs' negligent misrepresentation claims must be dismissed for failure to plead reliance.

III. MOTION TO STRIKE PLAINTIFFS' REFERENCES TO OTHER LITIGATION

Defendants also move the Court to strike a portion of Plaintiffs' pleadings as immaterial pursuant to Rules 8(a)(2) and 12(f). The portion of the pleadings in question involves a recitation of proceedings in other cases against Defendants. Plaintiffs contend that the rulings in other litigation referenced in those paragraphs constitute *res judicata* on a number of issues before the

Court in this matter, but Plaintiffs do not object to removing these allegations from the complaint. Therefore, the Court strikes ¶¶ 64–86 of the amended complaint.

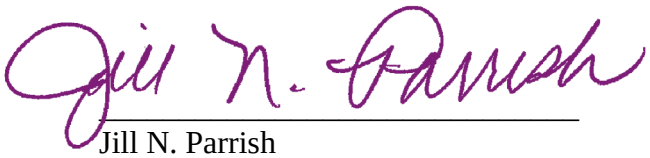
IV. ORDER

For the reasons above:

1. The Court will issue a separate order certifying to the Utah Supreme Court the issue of comment k's application to implanted medical devices in Utah.
2. The Court orders the parties to meet, confer, and submit a proposed statement of facts and proposed questions for certification. They shall submit those to the court within fourteen days of this order. If the parties cannot agree upon stipulated facts or questions for certification, they shall submit their own proposals within the same period of time.
3. The Court will defer ruling on Plaintiffs' design defect claims arising in strict liability. However, discovery may proceed on those claims.
4. Plaintiffs' breach of express warranty claim is **DISMISSED WITHOUT PREJUDICE**.
5. Plaintiffs' negligent misrepresentation claims are **DISMISSED WITHOUT PREJUDICE**.
6. Paragraphs 64–86 of the amended complaint are **STRICKEN** pursuant to Rule 12(f).
7. Plaintiffs shall have thirty days from entry of this order to file a second amended complaint.

Signed January 22, 2018

BY THE COURT



Jill N. Parrish
United States District Court Judge